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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,056	11/27/2001	Alice A. Jacobs	12877-006001	1285

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EXAMINER	
HORLICK, KENNETH R	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/996,056	JACOBS ET AL.	
	Examiner	Art Unit	
	Kenneth R Horlick	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,20-23 and 35-41* is/are pending in the application.

4a) Of the above claim(s) *35-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,20-23,40 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/2/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. It is noted that this application is now being handled by a different examiner.

2. Applicant's election without traverse of Group I, claims 1-18, 20-23, 40, and 41 in the reply filed on 7/19/04 is acknowledged.

3. Claims 35-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/19/04.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Claims 1-17, 20-23, and 40-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are confusing because of the improper Markush language "selected from the group comprising" in amended/new claims 1, 10, 21, and 40.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8,11-18, 20, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Balch.

Balch discloses a method of determining cause of one or more medical symptoms by obtaining a biological sample from subject, obtaining an array of different probes that selectively interact with target associated with different known cause of one or medical symptoms, applying sample to probes so they interact, detecting and analyzing and the device and system of using such an array (see whole document esp. abstract, col. 5, lines 16-30, particularly col. 8 & col. 34 lines 5-12). This reference discloses the use of probes which are nucleic acids, antigens or antibodies (see col. 1, lines 25-30). Also disclosed is testing human samples or DNA (see col. 33 line 57 & 66). Also disclosed is use of thiol or amino groups for covalent binding of ligands (see col. 21 line 35-40).

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Amended/new claims 10 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balch.

These claims are drawn to methods as rejected above, with the further limitation that the array includes four or more different probes or sets of probes (claim 10), or five or more different probes or sets of probes (claim 40).

While Balch discloses multiplex analysis for several different targets, targeting four or five targets is not explicitly taught.

One of ordinary skill in the art would have been motivated to apply the methods of Balch to at least four or five different targets because Balch clearly discloses multiplex analysis and, for example, "determining which infectious agent out of a panel

of possible organisms is causing a specific set of disease symptoms", and "analyzing and quantitating several molecular targets within a sample substance using an array having a plurality of biosites upon which the sample substance is applied". Undoubtedly, one of ordinary skill in the art would have understood a "panel of possible organisms" and "several molecular targets" to include four or five such organisms or targets. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

8. Claims 9 and 11 (tissue biopsy embodiment) are rejected under 35 U.S.C. 103(a) as being unpatentable over Balch in view of Au-Young et al.

The teachings of Balch are described previously.

Balch does not teach samples obtained from deceased individuals, or tissue biopsies.

Au-Younc teach testing autopsy biopsies to detect disease related nucleic acids (see col. 14 lines 40-50).

One of ordinary skill in the art would have been motivated to apply Au-Young et al.'s teachings of autopsied biopsies to Balch's assay in order to detect disease agents post mortem. It was well known and commonly practiced in the art to test samples from deceased individuals to confirm and diagnose diseases. As Au-Young et al teach testing samples from autopsied biopsies from serum, amniotic fluid or muscle samples, it would have been prima facie obvious to apply Au-Young et al.'s teaching of testing

samples from deceased individuals to Balch's detection method in order to confirm and diagnose the causative diseases in expired individuals.

9. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balch in view of Persing et al.

The teachings of Balch are described previously.

Balch do not teach therapeutic optimization factor.

Persing et al. teach detecting *M. tuberculosis* mutants, particularly rifampin resistant, by using probes that target rpOB (see whole doc. esp. abstract).

One of ordinary skill in the art would have motivated to apply Persing et al's teachings of detecting drug resistance genes to Balch's detection method in order to detect patients who have drug resistance pathogens. It would have been *prima facie* obvious to detect drug resistance in pathogens as taught by Persing et al. in order to correctly confirm disease diagnosis such as TB and provide for a correct drug regimen.

10. With respect to the above rejections, the arguments of the response filed 03/08/04 have been fully considered, but are not found persuasive. First, it is argued that Balch does not teach probes directed to targets such as self-antigens, poisons, or genetic disorders. For a teaching of probes targeting genetic disorders, applicant is directed to, for example, column 33, lines 50-66. Targeting poisons (or toxins) is covered in column 8, particularly in lines 24-27 and 63-67.

The response also argues, regarding claim 18, that Balch does not link diagnostic tests of genetic disorders to medical symptoms. However, this is not found convincing because, as is well understood in the art, genetic disorders are generally associated with one or more medical symptoms.

Regarding claims 9 and 11, the response only argues about the Balch patent, which is discussed above.

Regarding claims 21-23, the response argues that neither Balch nor Persing et al. describe the use of an array that includes the claimed first probe. However, this is not accurate as pointed out above, as Balch does indeed disclose probes targeting both poisons (toxins) and genetic disorders.

11. No claims are free of the prior art.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kenneth R. Horlick, Ph.D.

Kenneth R Horlick
Primary Examiner
Art Unit 1637

10/07/04